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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MEDTRONIC, INC.

Appeal 2009-010129
Application 10/656,855
Technology Center 3700

Before RICHARD E. SCHAFER, JAMESON LEE, and
RICHARD TORCZON, *Administrative Patent Judges*.

LEE, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

A. STATEMENT OF THE CASE

This is a decision on appeal by the real party in interest, Medtronic Inc. (Medtronic) under 35 U.S.C. § 134(a) from a final rejection of claims 11, 12, 14-34, and 37-41. We have jurisdiction under 35 U.S.C. § 6(b).

We *affirm-in-part*, and enter a new ground of rejection for claim 16.

References Relied on by the Examiner

Sato	Pat. 4,596,577	June 24, 1986
Dzau et al. (Dzau)	Pat. 6,352,555	March 5, 2002

The Rejections on Appeal

The Examiner rejected claims 11, 12, 14-17, 19, 20, 22 and 33 under 35 U.S.C. § 102(b) as anticipated by Sato.

The Examiner rejected claims 19, 23-30 and 32-34 under 35 U.S.C. § 102(b) as anticipated by Dzau.

The Examiner rejected claims 18, 21, 31, 32, 34, and 37-41 under 35 U.S.C. § 103 as unpatentable over Sato.

The Invention

Medtronic's invention relates to materials and devices implantable in a human body, such as materials and devices used in vascular prostheses. (Spec. ¶ 1). In particular embodiments, the biocompatible material -- expanded polytetrafluoethylene (ePTFE) -- is used to make a synthetic vascular graft in a tube-shaped prosthesis, and the graft includes a lumen through which blood flows. (Spec. ¶ 3). Medtronic's disclosure indicates that it is highly beneficial for a synthetic vascular graft to include a layer of endothelial cells in the lumen, to prevent thrombosis and to suppress abnormal smooth muscle cell proliferation that could lead to stenosis or

narrowing of the vessel. (Spec. ¶ 5). It is advantageous to seed the vascular graft by depositing harvested endothelial cells on the surface of the graft facing the lumen. (Spec. ¶ 5).

Medtronic discloses that in a vascular prosthesis made of ePTFE, the luminal surface includes microscopic nodes and fibrils that cooperate to give the material its strength and physical properties. (Spec. ¶ 7). Medtronic also discloses that by physically processing the luminal surface, such as by rubbing or applying force to the surface with a pressurized fluid, nodes can be lifted from the luminal surface and recesses can be formed to receive the endothelial cells. (Spec. ¶ 7). In the absence of these recesses, endothelial cells deposited on the graft tend to be exposed and washed away by the flow of blood, and when the cells wash away, there is greater risk of developing complications. (Spec. ¶ 8).

The independent claims are claims 11, 19, 25, 33, and 37. All are method claims. They are drawn to various aspects of a synthetic vascular graft and are reproduced below:

> Claim 11: A method comprising rubbing a luminal surface of a vascular prosthesis with a tool to lift nodes from the luminal surface to define a plurality of recesses.
>
> Claim 19: A method comprising applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface including expanded polytetrafluoroethylene, to lift nodes from the surface to define a plurality of recesses.
>
> Claim 25: A method comprising:
>
> applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface comprising nodes formed of

polytetrafluoroethylene, to lift nodes from the surface to define a plurality of recesses, and seeding cells on the surface.

Claim 33: A method for treating a luminal surface of a vascular prosthesis that comprises expanded polytetrafluoroethylene, the luminal surface comprising nodes and fibrils, the method comprising

applying a frictional force to the luminal surface to lift at least some of the nodes from the luminal surface and form recesses, wherein the lifted nodes are substantially free of attached fibrils.

Claim 37: A method for treating a luminal surface of a vascular prosthesis that comprises expanded polytetrafluoroethylene, wherein the luminal surface comprises nodes and fibrils oriented to interconnect the nodes, and wherein the vascular prosthesis has a generally tube-shaped structure having an axis, the method comprising

rubbing the luminal surface with a brush in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils to lift the nodes from the luminal surface and from recesses.

B. PRINCIPLES OF LAW

Anticipation under 35 U.S.C. § 102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Where the Patent Office has reason to believe that a functional feature in the claimed subject matter may in fact be an inherent characteristic of the prior art, it may require the patent applicant to prove that the subject matter

shown to be in the prior art does not possess the characteristic relied on. *In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971).

During examination, a claim term is construed according to its broadest reasonable interpretation. *In re Bigio*, 381 F.3d 1320, 1324. (Fed. Cir. 2004). Absent claim language carrying a narrow meaning, the USPTO should only limit the claim based on the specification when it expressly disclaims the broader definition. *Id.* at 1325.

C. FINDINGS OF FACT

1. Sato discloses a tubular vascular prosthesis made of polytetrafluoroethylene, and a method for forming the same. (Sato Abstract).

2. Sato discloses that its vascular prosthesis material can be made of expanded polytetrafluroethylene. (Sato 3:32-42).

3. Sato refers to its vascular prosthesis as an artificial arterial tube and states that it comprises a stretched and baked polytetrafluoroethylene tube having an inner surface on which a nap is uniformly formed. (Sato 4:29-32).

4. Sato discloses that the nap can be provided on the outer surface of the tube or both the inner and outer surfaces of the tube. (Sato 4:32-34).

5. Sato discloses that a nap can be raised on the surface of the material when frozen if, for example, a rotary brush having relatively soft wires is rubbed against the surface. (Sato 3:64-67).

6. Sato discloses that a method for forming the vascular prosthesis comprises impregnating fluororesin material having continuous pores with water, freezing it, raising a nap thereon, and defrosting and dewatering it. (Sato, Abstract).

7. Dzau discloses a method for implanting cells onto a prosthesis, including the steps of (a) providing a prosthesis including a porous tube, (b) contacting the prosthesis with a suspension of cells, and (c) providing a pressure differential between the inner surface and the outer surface of the prosthesis. (Dzau Abstract).

8. Dzau discloses that in one embodiment, its prosthesis is a vascular graft. (Dzau 2:42-43 and 56-57).

9. Dzau discloses that its prosthesis can be made of any biocompatible porous material and that preferred materials include polytetrafluoroethylene (PTFE). (Dzau 5:10-12).

10. For seeding cells on the prosthesis, Dzau discloses injecting fluid medium containing the cells into the lumen of the prosthesis, under a pressure gradient in which the pressure on the interior of the prosthesis is higher than the pressure on the exterior. (Dzau 5:57-61).

D. ANALYSIS

The Anticipation Rejection over Sato

The Examiner rejected claims 11, 12, 14-17, 19, 20, 22 and 33 under 35 U.S.C. § 102(b) as anticipated by Sato.[2] (Ans. at 4). Of these rejected claims, claims 11, 19, and 33 are independent claims. Claims 12 and 14-17 depend from claim 11, and claims 20 and 22 depend from claim 19.

Claim 11 recites a single step method. The step is "rubbing a luminal surface of a vascular prosthesis with a tool." The claim further recites the

[2] We regard the identity of those claims rejected for anticipation by Sato as that stated in the Examiner's Answer and not that stated in the Final Office Action.

function performed by the process step, *i.e.*, "to lift nodes from the luminal surface to define a plurality of recesses."

Claim 19 recites a single step method. The step is "applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface including expanded polytetrafluroethylene." The claim further recites the function performed by the process step, *i.e.*, "to lift nodes from the surface to define a plurality of recesses."

Claim 33 recites a single step method. The step is "applying a frictional force to the luminal surface [of a vascular prosthesis that comprises expanded polytetrafluroethylene]." The claim further recites the function performed by the process step, *i.e.*, "to lift at least some of the nodes [on the luminal surface] from the luminal surface and form recesses, wherein the lifted nodes are substantially free of attached fibrils."

Sato discloses a tubular vascular prosthesis made of polytetrafluoroethylene, and a method for forming the same. (Sato. Abstract). Sato discloses that its vascular prosthesis material can be made of expanded polytetrafluroethylene. (Sato 3:32-42). Sato discloses a tubular vascular prosthesis which inherently has an internal lumen and a luminal surface, and Sato discloses that a nap is uniformly formed on the internal lumen surface. (Sato 4:29-32). Sato discloses that a nap can be raised on the surface of the material when frozen if, for example, a rotary brush having relatively soft wires is rubbed against the surface. (Sato 3:64-67).

Anticipation under 35 U.S.C. § 102(e) requires that each and every element as set forth in the claim is found, either expressly or inherently

described, in a single prior art reference. *In re Robertson*, 169 F.3d at 745; *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d at 631.

Based on the disclosure of Sato as noted above, the Examiner correctly determined that Sato discloses the single step recited in each of independent claims 11, 19, and 33. Sato's disclosure of brushing the luminal surface of a vascular prosthesis made of ePTFE fully meets the limitations of rubbing the luminal surface of a vascular prosthesis with a tool (claim 11), applying a frictional force to an implantable medical device having a surface including ePTFE (claim 19), and applying a frictional force to the luminal surface of a vascular prosthesis that comprises ePTFE (claim 33).

Medtronic asserts that the Examiner has not established that Sato discloses the function and result recited in claims 11, 19, and 33, which is accomplished by the recited process step. The argument is misplaced and rejected. Where the Patent and Trademark Office has reason to believe that a functional feature in the claimed subject matter may in fact be an inherent characteristic of the prior art, it may require the patent applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. *In re Swinehart*, 439 F.2d at 213. The Patent and Trademark Office has neither the facility nor the personnel to conduct actual experimentation and laboratory work. *In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986)("The PTO is not equipped to perform such tasks"); *In re Brown*, 459 F.2d 531, 535 (CCPA 1972)("the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.").

Here, Sato discloses the single process step recited in claims 11, 19, and 33, but does not refer to the same function and result identified in those

claims. Because the process step is the same, the Examiner has reason to believe that the same function and result referred to in the claims is also achieved by the process step disclosed in Sato. A prima facie case of anticipation is met and the burden of going forward with submission of proof to the opposite was properly placed on Medtronic. Medtronic's simply stating that the Examiner has not shown that the same function and result is obtained by the process step disclosed in Sato is misplaced and insufficient to overturn the conclusion of anticipation.

With respect to claims 11, 19, 33, and the rejected claims dependent thereon, Medtronic has not put forth any evidence or articulated any reason to establish that the rubbing step employed in Sato to raise naps on the luminal surface of a vascular prosthesis made of ePTFE does not lift nodes to form recesses on the luminal surface of the vascular prosthesis. Also, with respect to claim 33 and the rejected claims dependent thereon, Medtronic has not put forth any evidence or articulated any reason to establish that nodes lifted by the rubbing step of Sato would not be substantially free of fibrils.

Claim 16, which depends from claim 14 which depends from claim 11, additionally recites "wherein rubbing comprises moving the bristles in the luminal direction to cause the bristles to come in contact with the luminal surface." The Examiner stated (Answer 4:16): "since [the rubbing in Sato] occurs along the luminal surface it can be said it is rubbed in a luminal direction," citing column 4, lines 33-34. In the context of Medtronic's specification, the "luminal direction" is along the axis of the tubular prosthesis. (Spec. 5:3-4).

We are not sure what the Examiner means by occurs "along" the luminal surface. The cited portion of Sato contains no such language or any equivalent. Sato does not describe that its rotary brush is moved "along" in the luminal direction, or any direction, while contact is maintained with the contact surface. Medtronic also correctly notes that it is possible that the brush may be lifted from the surface when it is moved. The Examiner's finding that the limitation of moving the bristles in the luminal direction as a part of the rubbing step is met by Sato is not supported by the record.

For the foregoing reasons, we sustain the rejection of claims 11, 12, 14, 15, 17, 19, 20, 22, and 33 under 35 U.S.C. § 102(b) as anticipated by Sato. However, the rejection of claim 16 as anticipated by Sato cannot be sustained.

The Anticipation Rejection over Dzau

The Examiner rejected claims 19, 23-30, and 32-34 under 35 U.S.C. § 102(b) as anticipated by Dzau.[3] (Ans. at 4). Of these rejected claims, claims 19, 25, and 33 are independent. Claims 23, 24, and 32 depend from claim 19. Claims 26-30 depend from claim 25. Claim 34 depends from claim 33.

Claim 19 recites a single step method. The step is "applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface including expanded polytetrafluroethylene." The claim further recites the function

[3] We regard the identity of those claims rejected for anticipation by Dzau as that stated in the Examiner's Answer and not that stated in the Final Office Action.

performed by the process step, *i.e.*, "to lift nodes from the surface to define a plurality of recesses."

Claim 25 recites a two-step method. The first step is "applying a frictional force to a medical device, the medical device adapted to be implanted in a human body and including at least one surface comprising nodes formed of polytetrafluroethylene." The second step is "seeding cells on the surface." The claim further recites the function performed by the first step, *i.e.*, "to lift nodes from the surface to define a plurality of recesses."

Claim 33 recites a single step method. The step is "applying a frictional force to the luminal surface [of a vascular prosthesis that comprises expanded polytetrafluroethylene]." The claim further recites the function performed by the process step, *i.e.*, "to lift at least some of the nodes [on the luminal surface] from the luminal surface and form recesses, wherein the lifted nodes are substantially free of attached fibrils."

Dzau discloses a method for implanting cells onto a vascular prosthesis. (Dzau Abstract; 2:42-43 and 56-57). Dzau discloses that its prosthesis can be made of any biocompatible porous material and that preferred materials include polytetrafluoroethylene (PTFE). (Dzau 5:10-12). For seeding cells on the prosthesis, Dzau discloses injecting fluid medium containing the cells into the lumen of the prosthesis, under a pressure gradient in which the pressure on the interior of the prosthesis is higher than the pressure on the exterior. (Dzau 5:57-61).

The Examiner determined (Ans. 4:22 to 5:2) that the fluid medium injection step of Dzau constitutes the step of applying a frictional force to a medical device (claims 19 and 25) and applying a frictional force to the

luminal surface of a vascular prosthesis. That determination is reasonable and is not challenged by Medtronic.

Where the Patent and Trademark Office has reason to believe, that a functional feature in the claimed subject matter may in fact be an inherent characteristic of the prior art, it may require the patent applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. *In re Swinehart*, 439 F.2d at 213. The Patent and Trademark Office has neither the facility nor the personnel to conduct actual experimentation and laboratory work. *In re King*, 801 F.2d at 1327; *In re Brown*, 459 F.2d at 535.

With respect to the function performed by the recited process step of applying frictional force, the Examiner has a reasonable basis to believe that the fluid medium injection step of Dzau does the same, *i.e.*, to lift nodes from the medical deice or vascular prosthesis to define or form a plurality of recesses thereon as is recited in claims 19, 25, and 33. Because the claimed process step is disclosed by Dzau, the Examiner has reason to believe that the same function referred to in the claims is also achieved by the process step disclosed in Dzau. A prima facie case of anticipation is met and the burden of going forward with submission of proof to the opposite was properly placed on Medtronic.

Medtronic's stating that the Examiner has not shown that the same function is performed by the fluid medium injection step disclosed in Dzau is misplaced and insufficient to overturn the conclusion of anticipation. The record contains no declaration testimony from any Medtronic technical witness to the effect that Dzau's injecting step does not lift nodes or form

recesses. Medtronic has not shown that the fluid medium injection step of Dzau does not lift any node or form any recess.

Additionally, we note this apparently contrary indication from Medtronic's own specification, in paragraph 7: "by rubbing or applying force to the surface with a pressurized fluid, nodes can be lifted from the luminal surface, forming recesses that can receive the endothelial cells." And with respect to claim 33, Medtronic has not shown that nodes lifted by Dzau's fluid medium injecting step would not be substantially free of fibrils.

We also recognize that Dzau describes that the inner surface of its vascular prosthesis includes pores large enough to allow mammalian cells to enter, even prior to the step of injecting cells through the lumen (Dzau 4:66-67). However, that does not mean the injecting step lifts no node or creates no additional recess.

For the foregoing reasons, the rejection of claims 19, 23-30, and 32-34 under 35 U.S.C. § 102(b) as anticipated by Dzau is sustained.

The Obviousness Rejection based on Sato

The Examiner rejected claims 18, 21, 31, 32, 34, and 37-41 under 35 U.S.C. § 103 as obvious over Sato. (Ans. 5-6).

Claim 18 depends from independent claim 11. Claim 38 depends from independent claim 37. With regard to claims 18 and 38, the issue pertains to the feature of "everting the vascular prosthesis after rubbing." The claims also recite that the luminal surface is an outer surface of the prosthesis when the prosthesis is being rubbed.

According to the Examiner, when action is needed on the inside surface of a flexible tubular structure, it would have been obvious to one with ordinary skill to perform the action by flipping the inside surface to the

exterior to facilitate the action and then evert the tube afterwards. Medtronic asserts that the Examiner's position is conclusory, not supported by any reasoned motivation, and merely constitutes subjective musing and conjecture. (App. Br. 14:2-7). We are unpersuaded by Medtronic.

In an obviousness analysis, it is not necessary to find precise teachings in the prior art reflecting the specific subject matter claimed because inferences and creative steps that a person of ordinary skill in the art would employ can be taken into account. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). A person of ordinary skill in the art is also one of ordinary creativity and not an automaton. *Id. at* 421. It would have been evident to one with ordinary skill that a flexible tubular structure can be inverted to provide better access to the interior surface for processing such as rubbing. We find that the level of ordinary skill in the art is such that one with ordinary skill would have known about inverting a tubular structure to provide better access to its interior surface. The finding is supported by the lack of detailed instructions in Medtronic's specification on how to invert such a structure. In Paragraph 31, the specification simply states: "As shown in FIG. 2, vascular prosthesis 10 has been everted, *i.e.*, vascular prosthesis 10 has been turned "inside out" to facilitate processing with tool assembly 20." Also, in Paragraph 61, the specification states that "everting the prosthesis for processing is not essential to the invention."

Claim 31 depend from independent claim 11. Claims 21 and 32 depend from independent claim 19. Claim 34 depends from independent claim 33. Claims 38-41 depend from independent claim 37.

Claim 21 adds the feature of a direction of rubbing that is substantially perpendicular to an orientation of the nodes.

Claim 31 adds the feature of a direction of rubbing that is substantially parallel to the oriented fibrils which interconnect the nodes.

Claim 32 adds the feature of a direction of application of frictional force, that is substantially parallel to the oriented fibrils which interconnect the nodes.

Claim 34 adds the feature of a direction of application of frictional force, that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils which interconnect the nodes.

Claim 37 is an independent claim and reads as follows:

> 37. A method for treating a luminal surface of a vascular prosthesis that comprises expanded polytetrafluoroethylene, wherein the luminal surface comprises nodes and fibrils oriented to interconnect the nodes, and wherein the vascular prosthesis has a generally tube-shaped structure having an axis, the method comprises rubbing the luminal surface with a brush in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils to lift the nodes from the luminal surface and form recesses.

Claim 37 is similar to claim 33, except that it recites that the vascular prosthesis is tube-shaped and adds a direction of rubbing, that is substantially parallel to the axis of the prosthesis and oriented fibrils. Unlike claim 33, it does not require the lifted nodes to be substantially free of attached fibrils.

The issue here with respect to claims 21, 31, 32, 34, and 37-41 centers about the claimed direction of rubbing or application of frictional force, which has to be substantially perpendicular to the oriented nodes, substantially parallel to the oriented fibrils, or substantially parallel to the axis of the tubular vascular prosthesis.

According to Medtronic, the claimed features exclude the use of a rotary brush to rub or apply frictional force to the luminal surface of the prosthesis or medical device, such as that disclosed by Sato. We disagree.

During examination, a claim term is construed according to its broadest reasonable interpretation. *In re Bigio*, 381 F.3d at 1324. Absent claim language carrying a narrow meaning, the USPTO should only limit the claim based on the specification when it expressly disclaims the broader definition. *Id.* at 1325. Medtronic has pointed to no such disclaimer and none is apparent to us from Medtronic's specification.

For instance, translationally moving the rotary brush tool in a linear direction that is substantially perpendicular to an orientation of the nodes meets the claim feature in claim 21 of "rubbing the surface with the tool in a direction that is substantially perpendicular to an orientation of the nodes." Translationally moving the rotary brush tool in a linear direction that is substantially parallel to the oriented fibrils meets the claim feature in claim 31 of "rubbing the luminal surface in a direction substantially parallel to the oriented fibrils." Translationally moving the rotary brush tool in a linear direction that is substantially parallel to the axis of the prosthesis and the oriented fibrils meets the claim feature in claim 34 of "applying the frictional force in a direction that is substantially parallel to the axis of the vascular prosthesis and the oriented fibrils."

Sato discloses rubbing the luminal surface of a vascular prosthesis with a rotary brush tool. It does not describe any specific pattern for moving the rotary brush tool to cover the entire luminal surface but leaves that to the knowledge and skill of one with ordinary skill in the art. Also, based on

Sato it does not matter precisely how the rotary brush tool is moved from place to place on the luminal surface of the vascular prosthesis.

In an obviousness analysis, it is not necessary to find precise teachings in the prior art reflecting the specific subject matter claimed because inferences and creative steps that a person of ordinary skill in the art would employ can be taken into account. *KSR Int'l Co.,* 550 U.S. at 418. A person of ordinary skill in the art is also one of ordinary creativity and not an automaton. *Id. at* 421. Such a hypothetical person possesses common sense and does not need specific instructions on all details of matters within his or her skill. We find that the level of skill in the art is such that one with ordinary skill would have known to move the rotary brush tool of Sato in any direction to cover a large surface of the vascular prosthesis, including each of the linear directions recited in each of claims 21, 31, 32, 34, and 37.

Medtronic has submitted no declaration evidence to establish that translational movement of the rotary brush tool of Sato in each of the linear directions claimed by Medtronic would result in an inability to raise naps.

For the foregoing reasons, we sustain the obviousness rejection of claims 18, 21, 31, 32, 34, and 37-41.

New Ground of Rejection

Claim 16 depends from claim 14 which depends from claim 11. We have affirmed the anticipation rejection of claim 14 over Sato. Claim 16 reads as follows:

> The method of claim 14,
>
> wherein the vascular prosthesis has a generally tube-shaped structure having an axis,

wherein the luminal surface defines a luminal direction along the axis, and

wherein rubbing comprises moving the bristles in the luminal direction to cause the bristles to come in contact with the luminal surface.

Sato discloses, in one embodiment, a vascular prosthesis that is tube-shaped having a main axis. (Sato 4:27-32 and Figure 4). The tubular structure has on its inside a luminal surface which defines a luminal direction along the axis of the tube. (Sato Figure 4).

Sato does not explicitly describe moving its rotary brush tool of the tool in a linear luminal direction. However, for reasons discussed above in connection with the obviousness rejection of claims 21, 31, 32, 34, and 37, that would have been obvious to one with ordinary skill in the art. When the rotary brush tool is moved in that direction, the bristles of the brush are also moved in the same direction, and the claim limitation is sufficiently broad so as not to exclude the use of a rotational brush. When the bristles are moved in a linear direction along the axis of the tube, they inescapably come in contact with additional portions of the luminal surface, satisfying claim 16.

Accordingly, claim 16 is unpatentable under 35 U.S.C. § 103 for obviousness over Sato.

DECISION

The rejection of claims 11, 12, 14, 15, 17, 19, 20, 22, and 33 under 35 U.S.C. § 102(b) as anticipated by Sato is *affirmed.*

The rejection of claim 16 under 35 U.S.C. § 102(b) as anticipated by Sato is *reversed.*

The rejection of claims 19, 23-30, and 32-34 under 35 U.S.C. § 102(b) as anticipated by Dzau is *affirmed.*

The rejection of claims 18, 21, 31, 32, 34, and 37-41 under 35 U.S.C. § 103 as unpatentable for obviousness over Sato is *affirmed.*

Claim 16 is herein rejected under 35 U.S.C. § 103 as unpatentable for obviousness over Sato.

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b). This regulation states that "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Furthermore, 37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(v).

AFFIRMED-IN-PART

NEW GROUND OF REJECTION

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